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TX US biotechnology firm AutoImmune saw its shares crash 74% on September 1 to close at $1.40 following the announcement that its oral tolerance drug Colloral (collagen) had failed in Phase III development. By the end of the trading week (September 3), the firm's stock was selling at a miserly $0.84, a nasty turnaround for a company which was riding high on the back of its oral tolerance technology a couple of years ago with stock being traded around the $14 mark.

AutoImmune says that Colloral will be dropped from development and the firm will "immediately reduce its headcount and other operating expenses to conserve resources as we evaluate our strategic options to maximize shareholder value." The company told the Marketletter that it plans to cut its workforce by 96%, downsizing to eight staff from 26 immediately and then to two employees by the end of the month.

In the 772-patient trial, Colloral was found to be safe but did not meet the primary endpoint, which the spokeswoman said was achieving statistical significance in three out of the "core-four" parameters (tender joints, swollen joints, physician's global assessment and patient global assessment). While AutoImmune says that "substantial improvements" from baseline were observed in each of these measurements, the placebo response was "much greater than previously observed." In fact, the spokeswoman noted that, although the data were not publicly available at present, the placebo response was two times higher than in previous studies of the drug. Full data may be presented at a forthcoming rheumatology meeting, and the firm is considering switching the focus of Colloral to a nutraceutical product.

When asked whether the trial could be designed differently, the spokeswoman told the Marketletter that it "was perfect." Financially, however, the firm cannot keep funding the clinical development of Colloral. AutoImmune had continued its clinical development of the drug even though earlier trials had failed to demonstrate strong data. Two years ago, the company revealed that two Phase II trials of Colloral in RA had failed to yield statistically significant results (Marketletter May 19, 1997). However, the firm decided to pursue Phase III development following an independent re-analysis by statisticians who concluded that the drug was significantly more effective than placebo (Marketletter September 15, 1997).

General expectations for the drug were not high, particularly following the earlier failure of another mucosal tolerance program, **Myloral** (myelin basic protein) for multiple sclerosis which performed no better than placebo in Phase III trials.

Yet some investors may see this a good buying opportunity, with analysts pointing out that the company has a decent cash position with few liabilities; as of June 30, the firm had cash and cash equivalents of almost $9.7 million and the spokeswoman added that once liabilities have been paid, this will be down to around $7 million.

Ideal opportunity to buy?

Furthermore, AutoImmune has a very strong intellectual property position and is still conducting a number of other trials which are funded

externally. These include studies in new-onset type 1 diabetes (with Eli Lilly) and a pilot trial in chronic organ transplant rejection (results from both are due next year). Enrollment is continuing in a National Institutes of Health-funded long-term prevention study for type 1 diabetes.

Importantly, the firm also has an exclusive agreement with Teva Pharmaceutical for applications of AutoImmune's proprietary technology. The deal covers the development of an oral formulation of Teva's injectable multiple sclerosis drug Copaxone (glatiramer acetate) and an oral product for the treatment of myasthenia gravis, for which AutoImmune will receive milestone payments on product approval and royalties on any future sales. Teva is getting ready to start a Phase II/III trial of oral Copaxone with the first patient expected to be enrolled by year end, while the product for myasthenia gravis is also due to begin clinical development before the end of the year.

Despite speculation that the company's faith in the potential of inducing oral tolerance to antigens as a means of treating autoimmune disease may be misguided, AutoImmune says it still firmly believes in its technology. In a statement, the company said that "both basic and clinical research focused on enhancing the biological effect of [mucosal tolerance therapy] in patients will continue."

AutoImmune is currently assessing a number of different plans, including possible mergers and converting into a shell company while waiting for clinical data from its other ongoing trials to come through. The spokeswoman said that there has been interest from some firms in a merger, particularly as AutoImmune has such a strong IP position.

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